DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Narang Medical Limited
Mr. Vivek Narang
Director
46, Naraina Industrial Area, Phase-1
New Delhi 110028
India

November 25, 2015

Re: K150561
Trade/Device Name: NET Brand Small Fragment and Large Fragment Osteosynthesis Plating System, NET Brand of DHS/DCS Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: September 22, 2015
Received: September 29, 2015

Dear Mr. Narang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150561

Device Name
NET Brand Small Fragment and Large Fragment Osteosynthesis Plating System, NET Brand of DHS/DCS Plating System

Indications for Use *(Describe)*

NET Brand Small Fragment and Large Fragment Osteosynthesis System is intended for small and large bone fracture fixation, arthrodesis and osteotomy fixation. Examples include: fractures of the clavicle, scapula, humerus, olecranon, radius, ulna, distal femur, proximal tibia, tibial pilon, fibula, pelvis and acetabulum fractures; periprosthetic fractures; The use of locking plate/screw systems is suited for treatment of fractures in osteopenic bone. This system is not indicated for use in the spine.

NET Brand DHS/DCS plating system may be used for fixation of the fractures of proximal femur such as femoral neck, trochanteric, pertrochanteric or intertrochanteric zones.
The system is indicated for use in adult patients only. All implants are for single use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Premarket Notification 510(k) Summary As required by Section 807.92

General Company Information as required by 807:92 (a) (a.1)

Submitter's Name	:	Narang Medical Limited
Address		
Office	:	46, Community Center, Naraina Industria Area, Phase-1, New Delhi 110028
Factory	:	Plot Number D-4, Sector A-2, Tronica City, Loni, Ghaziabad, 201102
CONTACT PERSON NAME	:	Mr. Vivek Narang
TITLE	:	Director
PHONE NUMBER	:	+91-45554000
Dated	:	18-11-2015

This is a bundled submission.

Throughout the submission there is a mention of **NET** Brand Small Fragment and Large Fragment Osteosynthesis Plating System, **NET** Brand of DHS/DCS Plating System that represents the range of products covered under this 510(k) submission.

a.2: The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known

Proprietary Name:

NET Brand Small Fragment and Large Fragment Osteosynthesis Plating System,

NET Brand of DHS/DCS Plating System

Common or Usual Name:

Orthopaedic Bone Plates

Orthopaedic Bone Screws

Classification Name:

PLATES, FIXATION, BONE

SCREWS, FIXATION, BONE

Product Code:

HRS, HWC

Device Class:

II

Review Panel:

Orthopaedic

Regulation Number:

21 CFR 888.3030 and 21 CFR 888.3040

Variants/Types:

NET Brand Small Fragment and Large Fragment Osteosynthesis Plating System, **NET** Brand of DHS/DCS Plating System are further subdivided into following categories

S. No.	Category	Types
01	Small Fragment Osteosynthesis Plating System	Locking
02	Large Fragment Osteosynthesis Plating System	Locking
03	DHS/DCS Plating System	NA

Further Description:

NET Brand Small Fragment and Large Fragment Osteosynthesis Plating System consists of plates and screws in a variety of designs and sizes and made from Ti-6Al-4V alloy or stainless steel. Plates are provided in straight designs and in various geometric configurations that are commonly used in trauma and reconstructive surgery. Plates are provided with screw holes to accommodate non-locking and locking screws designs. Screws are provided in, 3.5mm Cortex Self-tapping, 4.5 mm Cortex self-tapping and 2.7mm self-tapping cortex locking, 3.5mm self-tapping Cortex Locking, 5.0 mm cortex Locking thread designs in various lengths. This system is not indicated for use in spine.

NET Brand of DHS/DCS Plating System made from Ti-6Al-4V alloy or stainless steel and consist of DHS/DCS Plates, lag Screw, compression screw, and 4.5 Cortex screw Self Tapping, The DHS plates are available with barrel length 25mm (short barrel) and 38mm (Standard barrel) and barrel angels varies in 130^0 to 150^0. The DCS plate is having angle of 95^0

The DHS/DCS Screw is available in total length from 50 to 145 mm, thread length 22mm, shaft diameter 7 mm and outer diameter of 12.5. The thread of DHS/DCS Screw has a buttress type.

The DHS/DCS Compression Screw can be used to achieve fracture compression. Its dimension is available with thread length 36mm and outer diameter 4.0 mm.

a3) IDENTIFICATION OF THE PREDICATE DEVICE:

For the purposes of US FDA's regulation of medical devices, **NET** Brand Small Fragment and Large Fragment Osteosynthesis Plating System, **NET** Brand of DHS/DCS Plating System are substantially equivalent in indications and design principles to the following predicate devices.

S. No.	Device Name	510(k) Number	Predicate Manufacturer's Name	Subject Device Name
1.	Synthes LCP Proximal Humerus Plate	K011815	Synthes (USA)	Filos - Proximal Humerus Safety Lock Plate 3.5 – Standard
2.	3.5 mm LCP Distal Humerus System	K033995	Synthes (USA)	Distal Humerus Safety Lock Plate 2.7/3.5, Dorsolateral
3.	3.5 mm LCP Distal Humerus System	K033995	Synthes (USA)	Distal Humerus Safety Lock Plate 2.7/3.5, Dorsolateral with Lateral Support
4.	3.5 mm LCP Distal Humerus System	K033995	Synthes (USA)	Medial Distal Humerus Safety Lock Plate 2.7/3.5mm
5.	Synthes Small Fragment Dynamic Compression Locking (DCL) System	K000684	Synthes (USA)	LC-DCP Safety Lock Plate 3.5
6.	Synthes Small Fragment Dynamic Compression Locking (DCL) System	K000684	Synthes (USA)	Safety Lock 'T' Plate 3.5, Right Angled
7.	Synthes Small Fragment Dynamic Compression Locking (DCL) System	K000684	Synthes (USA)	Safety Lock 'T' Plate 3.5, Oblique Angled
8.	Synthes Clavicle Hook Plate	K061753	Synthes (USA)	Clavicle Hook Safety Lock Plate 3.5
9.	Synthes Small Fragment Dynamic Compression Locking (DCL) System	K000684	Synthes (USA)	Reconstruction Safety Lock Plate 3.5 – Straight
10.	3.5 mm LCP Distal Humerus System	(K033995)	Synthes (USA)	Safety Lock Screw Ø 2.7mm - Self Tapping

11.	Synthes Small Fragment Dynamic Compression Locking (DCL) System	K000684	Synthes (USA)	Safety Lock Screw Ø 3.5mm - Self Tapping
12.	Synthes (USA) 3.5 mm and 4.5 mm Locking Compression Plate (LCP) System with Expanded Indications	K082807	Synthes (USA)	Broad LC-DCP Safety Lock Plate 4.5 /5.0
13.	Synthes (USA) 3.5 mm and 4.5 mm Locking Compression Plate (LCP) System with Expanded Indications	K082807	Synthes (USA)	Narrow LC-DCP Safety Lock Plate 4.5/5.0
14.	Synthes (USA) LCP Proximal Femur Plate and Screws	K030858	Synthes (USA)	Proximal Femoral Safety Lock Plate 4.5/5.0/7.3
15.	Synthes LCP Distal Femur Plates	K062564	Synthes (USA)	Distal Femoral Safety Lock Plate 4.5/5.0
16.	Synthes LCP Proximal Tibia Plate Synthes 4.5 mm Titanium LCP Proximal Tibia Plating System	For Stainless Steel Plate (K011978) For Titanium Plate K023802	Synthes (USA)	Proximal Lateral Tibial Safety Lock Plate 4.5/5.0
17.	Synthes Small Fragment Dynamic Compression Locking (DCL) System	K000684	Synthes (USA)	Safety Lock 'T' Plate 4.5/5.0
18.	Synthes Small Fragment Dynamic Compression Locking (DCL) System	K000684	Synthes (USA)	L Buttress Safety Lock Plate 4.5/5.0
19.	Synthes Small Fragment Dynamic Compression Locking (DCL) System	K000684	Synthes (USA)	T Buttress Safety Lock Plate 4.5/5.0
20.	Synthes 4.5 mm LCP Straight Reconstruction Plates	K051986	Synthes (USA)	Reconstruction Safety Lock Plate 4.5/5.0
21.	Synthes Large Fragment Dynamic Compression Locking (DCL) System	K000682	Synthes (USA)	Safety Lock Screw Ø 5.0mm

22.	Synthes Limited Contact-Dynamic Hip Screw Implant (LC-DHS)" for K923613 Synthes Titanium Limited Contact-Dynamic Hip Screw Implant (Ti LC-DHS)" for K953607	K 923613 K953607	Synthes (USA)	Dynamic Hip Compression Plate (with Dynamic Compression Holes)
23.	Synthes Limited Contact-Dynamic Hip Screw Implant (LC-DHS)" for K923613 Synthes Titanium Limited Contact-Dynamic Hip Screw Implant (Ti LC-DHS)" for K953607	K 923613 K953607	Synthes (USA)	Dynamic Hip Compression Plate - Short Barrel (with Dynamic Compression Holes)
24.	DYNAMIC CONDYLAR SCREW OR D.C.S	K840954	Synthes (USA)	DCS Plate 95° with Dynamic Compression Holes
25.	Synthes Dynamic Hip Plate	K 923613 K953607	Synthes (USA)	Standard Lag Screw, Ø 12.5mm
	Synthes Limited Contact-Dynamic Hip Screw Implant (LC-DHS)" for K923613 Synthes Titanium Limited Contact-Dynamic Hip Screw Implant (Ti LC-DHS)" for K953607	K 923613 K953607	Synthes (USA)	Compression Screw
26.	Synthes Cortical Screws	K112583	Synthes (USA)	Cortex Screw Ø 3.5mm, Self Tapping
27.	Synthes Cortical Screws	K112583	Synthes (USA)	Cortex Screw Ø 4.5mm, Self Tapping

These implants are sold non-sterile, the products have to be sterilized prior to use.

A5). (5) A statement of the intended use of the device

Indications for Use:

NET Brand Small Fragment and Large Fragment Osteosynthesis System is intended for small and large bone fracture fixation, arthrodesis and osteotomy fixation. Examples include: fractures of the clavicle, scapula, humerus, olecranon, radius, ulna, distal femur, proximal tibia, tibial pilon, fibula, pelvis and acetabulum fractures; periprosthetic fractures; The use of locking plate/screw systems is suited for treatment of fractures in osteopenic bone. This system is not indicated for use in the spine.

NET Brand DHS/DCS plating system may be used for fixation of the fractures of proximal femur such as femoral neck, trochanteric, pertrochanteric or intertrochanteric zones.

The system is indicated for use in adult patients only. All implants are for single use only.

a6). Summary of Technological Characteristics as compared to the predicate devices:

SUBSTANTIAL EQUIVALENCE INCLUDING COMPARISON WITH PREDICATE DEVICES

The subject device and the predicate devices have the same intended use and have the same technological characteristics. The subject and predicate devices are all fabricated from the same or similar materials and share similar design characteristics.

The subject and predicate devices encompass the same range of physical dimensions, are packaged using the same materials, and are to be sterilized by the same methods. Any differences in the technological characteristics do not raise new issues of safety or efficacy. Performance data provided to demonstrate substantial equivalence included engineering analysis and mechanical testing according to ASIM F382, ASTM F 384 and ASTM F543.

Overall, Small Fragment and Large Fragment Osteosynthesis System of Narang Medical Limited have the following similarities to the predicate devices:

* has the same intended use,

* uses the same operating principle,

* incorporates the same basic design,

* incorporates the same or very similar materials, and

* has similar packaging and can be sterilized using the same materials and processes.

Following is the summary of parameters in which the comparison has been verified:

S. No.	Characteristics	Predicate Device Versus New Device (Auxein Brand)	Remarks
01	Indications for use	Similar intended use in New Device and Predicate device	Equivalent
02	Material	Same material used in New Device and Predicate device	Equivalent
03	Performance Standards	Same performance standards used in both New Device as well as predicate device	Equivalent

04	Sterilization	Same method of sterilization used in both New Device as well as Predicate device	Equivalent
05	Dimensional Verification	Same dimensions found in both New Device as well as Predicate device	Equivalent

b1). Discussion on the non-clinical testing performed

Following are the applicable product standards considered for non-clinical standards

A: Material Standards

B: Performance Standards

A: Material Standards: The raw material standards are the first standards to be complied, as it ensures compliance to the materials to be used for manufacturing of metallic surgical implants.

following material standards have been adopted and complied:

1. ASTM F 136: Standard specification for wrought Titanium-6Aluminium-4Vanadium ELI (Extra low interstitial) Alloy for surgical implant applications.

2. ASTM F 138: Standard Specification for Wrought 18 chromium-14Nickel-2.5Molybdenum stainless steel bar and wire for surgical implants.

3. ASTM F 139: Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Sheet and Strip for Surgical Implants

B: Performance Standards:

The performance of **NET** Brand Small Fragment and Large Fragment Osteosynthesis Plating System, NET Brand of DHS/DCS Plating System has been verified as per the following standards

- ASTM F 382,
- ASTM F 384 and
- ASTM F 543
- **For Bone Plates:**

As per ASTM F 382 and ASTM F 384 Static Four Point Bend Test: Conforms, Dynamic Four Point Bend Test: Conforms

- **For Bone Screws:**

- As per ASTM F 543 :Torsional Properties: Conforms, Driving Torque : Conforms, Pull-out Test: Conforms

b2). Discussion on the clinical evaluation referenced and relied upon:

NET Brand Small Fragment and Large Fragment Osteosynthesis Plating System,

NET Brand of DHS/DCS Plating System are of similar design and pattern as well as similar indications for use. Therefore Clinical information was not necessary to demonstrate substantial equivalence.

CONCLUSION:

General, Safety and Performance conclusion:

S. No.	Parameter of Conclusion	Proposed Device	Predicate Device
01	Product Code	For Bone Plates: HRS For Bone Screws: HWC	Same
02	Regulation Number	For Bone Plates: 21CFR 888.3030 For Bone Screws: 21CFR 888.3040	Same
03	Regulatory Class	Class II	Class II
04	Indications For use	Same Indications For Use	Similar
05	Sterilization	Provided Non-Sterile and to be sterilized using Autoclaving Method to achieve SAL of 10^{-6} AAMI ST79, ISO 17665-1	Similar

06	Mechanical Test Performance	**For Bone Plates:** As per ASTM F 382 and ASTM F 384 - Static Four Point Bend Test Conforms - Dynamic Four Point Bend Test Conforms **For Bone Screws:** As per ASTM F 543 - Torsional Properties Conforms - Insertion Torque Conforms - Removal Torque Conforms - Axial Pull-out Test Conforms	Same
07	Material Standards	ASTM F 136, ASTM F 138 and ASTM F 139	Same

General, Safety and Performance Conclusion:

From the available data available we can justify that the **NET** Brand Small Fragment and Large Fragment Osteosynthesis Plating System, **NET** Brand of DHS/DCS Plating System are as safe, as effective and perform as same indications for use as that of already marketed predicate devices identified in a3. Of 510(k) summary.

Therefore, our devices can be considered safe and effective for their intended use.